K090749
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VILLA SISTEMI MEDICALI

MAY 18 2009

# 510(k) Summary or 510(k) Statement

## 510 (k) Summary

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

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|---|---|
| Submitter: | Villa Sistemi Medicali S.p.A.<br>via delle Azalee 3<br>20090 Buccinasco (MI)<br>ITALY<br>Registration # 8021091 |
| Contact Person: | Paolo Casagrande Santin<br>QA Manager<br>Phone: +39 02 48859 239<br>Fax: +39 02 48859 303<br>Email: p.casagrande@villasm.com |
| Designated Agent: | Bill Kostecki<br>Del Medical Imaging<br>QA/RA Manager<br>Registration # 9027610 |
| Date Prepared: | March 16, 2009 |
| Trade Name: | Rotograph EVO and Rotograph EVO D |
| Common Name: | Dental panoramic and cephalometric unit |
| Classification Name: | 872.1800 Unit, X-Ray, Extraoral With Timer |
| Predicate Devices: | The Rotograph EVO and Rotograph EVO D are compared with the following predicate devices:<br>• Villa Sistemi Medicali Strato X – model Strato 2000 (K002432),<br>• Villa Sistemi Medicali Strato X – model Strato 2000 Digital (K002432),<br>• AFP/Owandy EVApan Digital/K1VSM2000 dental panoramic sensor (K041120),<br>• Owandy IMAX CEPH digital X-ray sensor (K062403). |
| Product Description: | Rotograph EVO and Rotograph EVO D are conventional panoramic x-ray system utilizing either films and cassettes (Rotograph EVO) or digital imaging (Rotograph EVO D). Both models can be equipped with a cephalostat. The device can be equipped with accessories to fulfil different diagnostic needs. In digital configuration (Rotograph EVO D) the images are acquired by a CCD sensor and are displayed on a monitor, and image manipulation, archiving and communication are performed via a computer (not included in the device). |
| Indication for Use: | Rotograph EVO and Rotograph EVO D, panoramic x-ray imaging systems with cephalostat, are extraoral source x-ray systems, which are intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry. |
| Rationale for Substantial Equivalence: | Rotograph EVO and Rotograph EVO D have the same indication for use as the predicate devices. They share the same technological characteristics as the predicate devices. Minor technological differences do not raise any new questions regarding safety or effectiveness of the devices. |

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Safety and Effectiveness Information:

The device labeling contains operating instructions for safe and effective use of Rotograph EVO and Rotograph EVO D. The software development for this device follows documented processes for software design, verification and validation testing. Final device validation (see Appendix C) and risk assessment has been conducted, to identify potential design hazards that could cause an error or injury based on the use of this device. Appropriate steps have been taken to control all identified risks. The device has been tested for compliance to IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety. and its derivatives

Conclusion:

Rotograph EVO and Rotograph EVO D perform the same functions in the same environment as the predicate devices. They share the same technology as the predicate devices. They are based on well known technology. They are as safe and effective as the predicate devices. We believe they do not introduce any new potential safety risks and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2009

Mr. Paolo Casagrande Santin
Quality Assurance Manager
Villa Sistemi Medicali S.p.A.
Via delle Azalee 3
Buccinasco MI 20090
ITALY

Re: K090749
Trade/Device Name: Rotograph EVO and Rotograph EVO D
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD and MUH
Dated: March 16, 2009
Received: March 20, 2009

Dear Mr. Santin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

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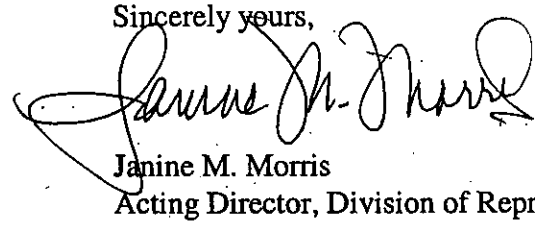
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology) | (240) 276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | (240) 276-0115 |
| 21 CFR 892.xxx | (Radiology) | (240) 276-0120 |
| Other | | (240) 276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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## Indications for Use Statement

### *Indications for Use*

510(k) Number (if known): K090749

Device Name: Rotograph EVO and Rotograph EVO D

Indications for Use:

Rotograph EVO and Rotograph EVO D, panoramic x-ray imaging system with cephalostat, are extraoral source x-ray system, which are intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090749